Paper No. 41

## UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MARC ALIZON,
FRANCOISE BARRE SINOUSSI,
PIERRE SONIGO,
PIERRE TIOLLAIS,
JEAN-CLAUDE CHERMANN,
LUC MONTAGNIER, and
SIMON WAIN-HOBSON

MAILED

JUN 2 7 2002

Appeal No. 2001-1870 Application No. 08/466,921 PAT. & T.M. OFFICE COARD OF PATENT APPE AND INTERFERE

#### ORDER REMANDING TO THE EXAMINER

Before STONER, Chief Administrative Patent Judge, HARKCOM, Vice Chief Administrative Patent Judge, and WILLIAM F. SMITH, Administrative Patent Judge.

WILLIAM F. SMITH, Administrative Patent Judge.

Our consideration of the record leads us to conclude that this case is not in consideration for a decision on appeal. Accordingly, we remand the application to the examiner to consider the following issues and to take appropriate action.

# Representative Claims

Claims 39 through 52 and 60 through 73 are pending. Claims 39 through 52, 60, and 61 have been allowed by the examiner while claims 62 through 73 are rejected.

Claims 39, 62, and 68 are representative of the subject matter claimed in this application:

- 39. A purified LAV λJ19 DNA fragment consisting of a restriction fragment generated by the <u>Bam</u>HI site at approximately 8150 to the <u>BG1</u>II site at approximately 9150.
- 62. A purified DNA fragment of HIV-1 consisting of a restriction fragment, wherein the fragment hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C.
- 68. An amplified copy of a DNA fragment of HIV-1, wherein said fragment hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C.

## **Discussion**

Claims 62 through 73 are rejected under 35 U.S.C. § 112, first paragraph (written description). Claims 68 and 69 are additionally rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Turning to the written description rejection, the examiner has determined that the purified DNA fragments encompassed by claims 62 through 73 do not enjoy written descriptive support in the original disclosure of this application. The examiner cites In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981); In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); and Bigham v. Godtfredsen, 857 F.2d 1415, 8 USPQ2d 1266 (Fed. Cir. 1988) in support of his rejection. See pages 4-6 of the Examiner's Answer. The Examiner's Answer in this case was entered on September 13, 2000. Since the claims on appeal are directed to DNA fragments, we find it curious that the examiner did not cite and apply the legal principles set forth in

University of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir.), cert. denied, 523 U.S. 1089 (1998)(Eli Lilly). Nor do appellants discuss this relevant case in their briefing before the board.

However, this error on the part of the examiner and appellants may have been overtaken by subsequent events. Specifically, the Court of Appeals for the Federal Circuit recently issued a decision which appears very relevant in determining the patentability of the claims on appeal, Enzo Biochem, Inc. v. Gen-Probe, Inc., 285 F.3d 1013, 62 USPQ2d 1289 (Fed. Cir. 2002). The claims under review in Enzo Biochem are similar to the rejected claims in this application in that both sets of claims were directed to a genus of nucleotide sequences defined by hybridization parameters. The court stated:

We conclude that, in this case, the district court correctly determined that the specification failed to provide an adequate written description of the claimed compositions. The court correctly found that the claimed nucleotide sequence is described only by its binding to N. gonorrhoeae in a preferential ratio of 'greater than about five' with respect to N. meningitidis. While that description of the ability of the claimed probe to bind to N. gonorrhoeaemay [sic] describe the probe's function, it does not describe the probe itself. We reject Enzo's characterization of the hybridization as a distinctive 'chemical property' of the claimed sequences. The hybridization distinguishes the claimed nucleotide sequences from unclaimed sequences only by what they do, which is a purely functional distinction.

Enzo attempts to distinguish the facts of this case from those in <u>Eli Lilly</u> by asserting that its claimed probes perform a different function (hybridization) than that of the claimed sequences in <u>Eli Lilly</u> (encoding proteins), and that the former function is descriptive in the context of probes. We do not find that distinction relevant because hybridization from one DNA segment to another is just as much a functional definition as translation from a nucleic acid to a protein. As stated above, a description of genetic material by what it does – such as hybridizing to <u>N</u>.

gonorrhoeae – is insufficient to satisfy § 112, ¶ 1, regardless whether the described property is labeled 'chemical' or 'functional.'

Enze Blochem needs to be considered by both the examiner and appellants in the first instance for another reason. The arguments presented by appellants in this appeal in regard to the written description rejection are cast in terms of appellants' purported "possession of the claimed invention." See, e.g., page 8 of the Appeal Brief. The court discussed in Enzo Biochem the role the so-called "possession" test has in determining whether given claimed subject matter enjoys written description in the original disclosure of a patent application. Enzo Biochem, 285 F.3d at 1021, 62 USPQ2d at 1294-1295.

Upon return of the application, the examiner should consider the issue of written description of claims 62 through 73 in light of the principles enunciated in Enzo Biochem. The court's decision may provide substantial support for the examiner's ultimate position regarding the patentability of claims 62 through 73 in regard to this requirement of the patent statutes as well as providing an answer to appellants' main position in this appeal. This board serves as a board of review. 35 U.S.C. § 6(b). Thus, prior to the board reaching a decision in the issues raised in this rejection, we need an exchange of views between the examiner and appellants as to the effect, if any, the court's decision in Enzo Biochem has on the patentability of claims 62 through 73.

We believe the examiner should also take a step back and review the patentability of allowed claims 39 through 52, 60, and 61 in light of the legal principles

set forth in <u>Eli Lilly</u> and <u>Enzo Biochem</u>. As set forth above, it does not appear that the examiner considered <u>Eli Lilly</u> in determining the patentability of any claim pending in this application. Furthermore, the subsequent issuance of the decision in <u>Enzo Biochem</u> may affect the examiner's decision to allow claims 39 through 52, 60, and 61.

We state that we are <u>not authorizing</u> a Supplemental Examiner's Answer under 37 CFR § 1.193(b)(1).

This application, by virtue of its "special" status, requires an immediate action.

Manual of Patent Examining Procedure § 708.01 (7th ed., rev. 1, February 2000). It is important that the Board be informed promptly of any action affecting the appeal in this case.

Remand

Bruce H. Stoner, Jr., Chief
Administrative Patent Judge

Gary V. Harkcom, Vice Chief Administrative Patent Judge

William F. Smith

Administrative Patent Judge

**BOARD OF PATENT** 

APPEALS AND

) INTERFERENCES

Appeal No. 2001-1870 Application No. 08/466,921

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